

- Group I: Claims 1-93 and 113-120, drawn to an analyte monitoring system.
- Group II: Claims 94-103, drawn to an insertion kit.
- Group III: Claims 104-107, drawn to a method of using an electrochemical sensor.
- Group IV: Claim 108, drawn to a method of detecting failure in an analyte responsive sensor.
- Group V: Claims 109-112, drawn to a method of calibrating.

In a telephone conversation on April 22, 1999, the Applicants' representative Bruce E. Black made a provisional election of Group I, claims 1-93 and 113-120, drawn to an analyte monitoring system. The Applicants affirm this election of Group I. The Applicants reserve the right to pursue the remaining claims in divisional or continuation applications.

#### **Information Disclosure Statement**

The Applicants filed an extensive Information Disclosure Statement on July 23, 1998, with Supplemental Information Disclosure Statements on March 17, 1999 and May 26, 1999. The first document was filed about nine months prior to the mailing of the present Office Action. An initialed copy of the accompanying Form 1449, indicating that the Examiner has reviewed all of the references, did not accompany the Office Action. The Applicants request that the Examiner send an initialed copy of the Forms 1449 so that the Applicants can ensure that all of the cited references have been reviewed. If the Examiner has any questions about these documents, the Applicants request that the Examiner contact the Applicants' representative, Bruce E. Black.

#### **Rejection under 35 U.S.C. §112, second paragraph**

Claims 1-39 and 80-84 were rejected under 35 U.S.C. §112, second paragraph. Claims 1-39 were rejected for not providing antecedent basis of "the sensor" in claim 1. Claim 1 has been amended to recite "the electrochemical sensor" for which there is antecedent basis in the claim.

Claims 80-84 were rejected for not providing antecedent basis for "the one or more physiological characteristics." Claims 80, 83, and 84 have been amended to recite "the patient-specific data" for which antecedent basis is provided in claim 79.

Accordingly, the Applicants request that the Examiner remove this rejection of claims 1-39 and 80-84.

**Rejection under 35 U.S.C. §102**

Claims 1-10, 17-19, 20-22, 24-28, 41, 43, 45-47, 51-59, 62-68, 71-78, 87-88, 113-116, and 118-120 were rejected under 35 U.S.C. §102(e) as being unpatentable over U.S. Patent No. 5,791,344 to Schulman et al. (hereinafter "Schulman"). The Applicants traverse this rejection for the reasons set forth below.

Independent claims 1 and 46 have been amended to recite a sensor control unit having a housing and an rf transmitter disposed in the housing. Schulman does not teach or suggest the use of an rf transmitter in a sensor control unit that is adapted for placement on the skin. The Office Action asserts that Schulman uses a transmitter (indicated in the Office Action as numeral 142, but should be numeral 156 of Figure 7B of Schulman), however, at best, this alleged transmitter is one coil of a transformer to provide for contactless coupling to a monitor. This coil is not an rf transmitter. Moreover, the transformer coupling scheme described in Schulman provides for severely limited range (i.e., the two coils must be very close to permit coupling of signals from one coil to another). Thus, the device described in Schulman can only be used when the patient is confined to bed or has very restricted movement.

In contrast, the Applicants have invented a sensor control unit that allows much more movement because the rf transmitter of the sensor control unit does not need to be in close proximity to the rf receiver of the display unit. In one embodiment, the sensor control unit is disposed on the abdomen of the user and the display unit is looks like a portable pager and is carried in a pocket or worn on a belt or other item of clothing of the user.

For at least these reasons, independent claims 1 and 46 are patentable over Schulman. The remainder of the rejected claims, except claim 45, depend from claim 1 or claim 46 and are patentable over Schulman for at least the same reason. These claims also include other features that are patentable over Schulman. Accordingly, the Applicants request the withdrawal of the rejection of claims 1-10, 17-19, 20-22, 24-28, 41, 43, 46-47, 51-59, 62-68, 71-78, 87-88, 113-116, and 118-120.

Claim 45 recites a sensor assembly comprising a sensor having at least one recessed channel formed in the surface of the substrate where conductive material is disposed in the channel to form at least one working electrode. Schulman does not teach a sensor having these characteristics. At best, Schulman illustrates a sensor with a working electrode formed on top of a substrate. Thus, claim 45 is not anticipated by Schulman because Schulman does not teach every limitation, as required for a rejection under 35 U.S.C. §102(e). Moreover, Schulman does not suggest this type of sensor or motivate the modification of the illustrated sensor to have the structure recited in claim 45. Therefore, claim 45 is not obvious in view of Schulman. Accordingly, the Applicants request the withdrawal of the rejection of claim 45.

The Applicants also note a number of irregularities in the Office Action. All of the claims rejected by citation of art were rejected under 35 U.S.C. §102(e). A rejection under 35 U.S.C. §102(e) requires that the cited reference anticipate the rejected claim. A reference anticipates a claim if the reference teaches each of the elements of the claim. In the rejection of the claims under 35 U.S.C. §102(e), the Office Action indicated a number of items that Schulman does not teach, but which the Office Action finds anticipated. For example, claim 19 was rejected because "the examiner's position [is] that any battery of any kind is removable from a housing." Claims 24, 25, and 26 were rejected as anticipated by Schulman even though "Schulman does not disclose an electrical shock, vibration or increasing alarm" because "it would have been obvious to one in that art that the disclosed alarm indication means is obvious in the art." Claims 62 and 63 were rejected as anticipated by Schulman because "it is the examiner's position that any device is portable and can be worn on a piece of clothing", despite the fact that there is no disclosure of a portable sensor control unit in Schulman. In each of these cases, Schulman did not teach each element of the claims, but the Office Action asserts that those elements would be obvious. Such a rejection is properly made under 35 U.S.C. §103 by satisfying the requirements for presenting a prima facie case of obviousness.

In addition, many of the dependent claims were indicated as being anticipated without any explanation as to how Schulman taught the elements of the claim. In many instances, Schulman did not teach or disclose, much less suggest, these elements. For example:

Claim 8            Schulman does not teach a housing comprising a base and a cover.

- Claim 20 Schulman does not teach a sensor control unit having an alarm (in Schulman, the alarm is in the display unit.)
- Claim 22 Schulman does not teach using a reed switch, Hall effect switch, or gigantic magnetic ratio switch to deactivate an alarm.
- Claims 28, 54 Schulman does not teach having a receiver disposed in a housing of a sensor control unit that is adapted for placement on the skin.
- Claim 41 Schulman does not teach a transmitter in a sensor control unit that is configured for encrypting data.
- Claim 62 Schulman does not teach a portable display unit.
- Claim 64 Schulman does not teach having a secondary display unit in addition to the portable display unit.
- Claim 68 Schulman does not teach having a display unit with an alarm that activates if a signal is not received from the sensor control unit at a predetermined time interval.

These are only some examples of the claims that are not anticipated, much less obvious, in view of Schulman. The Applicants request that the Examiner provide indications as to why these claims are anticipated by Schulman, if the rejection is maintained.

### Conclusion

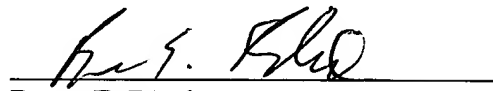
In view of the amendments to the claims and the arguments presented herein, the Applicant respectfully submits that each of the presently pending claims (claims 1-93 and 113-127) is in condition for allowance and notification to that effect is respectfully requested. The

Examiner is invited to contact Applicants' representative at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted,

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DATE: July 26, 1999

  
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